## REMARKS

Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks. Claims 33-86 are pending; claims 73-80 are currently under examination, and claims 33-72 and 81-86 are withdrawn. Claim 73 is amended to particularly point out and distinctly claim certain embodiments of the Applicant's invention, and to comply with the Office Communication of December 11, 2010. Specifically, claim 73 is amended to include "biochanin A," and thus remain consistent with Applicant's original election of "formonetin and biochanin." No new matter has been added by the amendment, support for which can be found in the claims as originally filed. In view of this amendment, Applicant's response to the Office Action of April 2, 2009 are re-iterated below.

### EFFECTIVE FILING DATE

The Examiner asserts that claims 73 and 76-80 are not entitled to the priority filing date of 5/1/1998, alleging that the as-filed specification fails to describe a composition in which the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less. However, the Examiner agrees that claims 74 and 75 are entitled to the priority filing date of 5/1/1998.

Applicant respectfully disagrees. Nonetheless, without acquiescence, the subject matter of claim 73 has been amended to incorporate the subject matter of previous claim 74 (now canceled), which the Examiner agrees is supported by the as-filed specification. Hence, Applicant submits that each of the currently pending claims is entitled to the priority filing date of 5/1/1998, and kindly requests the Examiner to accord the claims that priority date.

### REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Claims 73 and 76-80 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. The Examiner alleges that the as-filed specification does not provide descriptive support for the recitation "wherein the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less," and then asserts that this recitation represents new matter.

Applicant traverses this rejection and submits that the specification reasonably conveys to persons skilled in the art at the time of filing that Applicant possessed the presently claimed subject matter, including compositions in which the level of biochanin A is about 10% w/w or less of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less. For instance, the specification at page 9, lines 24-25 explicitly discloses a composition in which "***genistein, if present, is in the amount of about 5% w/w or less***." Further, the specification at page 9, lines 21-22 explicitly discloses that the instant compositions "may contain minor amounts of ***other isoflavones, in the order of 10% or less***." Since the specification focuses mainly on three ***other isoflavones*** (*i.e.,* daidzein, genistein, and biochanin A), persons skilled in the art would readily identify biochanin A as one of these ***other isoflavones*** that can be present at about 10% or less, as recited in the instant claims.

Nonetheless, without acquiescence and merely to expedite prosecution of certain embodiments of Applicant's invention, claim 73 as amended herewith incorporates the subject matter of claim 74, which was not rejected under this section. Hence, amended claim 73 relates, in pertinent part, to a composition for the treatment or reduction of menopausal symptoms in a post-menopausal woman, said composition comprising an effective amount of formononetin and biochanin A, ***wherein the formononetin represents at least about 90% of the isoflavone content***, and wherein genistein, if present, is in the amount of about 5% w/w or less.

Applicant submits that the amendment to claim 73 obviates this rejection under 35 U.S.C. § 112, first paragraph, and respectfully requests withdrawal of the same.

**REJECTION UNDER 35 U.S.C. § 103**

Claims 73-80 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Kelly (WO 1993/23069). The Examiner agrees that this reference does not expressly disclose a composition comprising 90-95% formononetin and 10% or less of other isoflavones, but asserts that it would have been obvious to prepare such a composition, mainly because Kelly allegedly teaches the use of phytoestrogens from the hypocotyls of soya, which the Examiner asserts to contain 95% daidzein and 5% genistein, and also allegedly teaches the unimportance of whether the isoflavones are in their methylated or demethylated forms.

Applicant respectfully traverses this rejection and submits that the instant claims satisfy the requirements of non-obviousness over Kelly. The present claims relate, in pertinent part, to compositions for the treatment or reduction of menopausal symptoms in a post-menopausal woman, comprising an effective amount of formononetin and biochanin A, wherein the formononetin represents at least about 90% of the isoflavone content, and wherein genistein, if present, is in the amount of about 5% w/w or less.

Kelly fails to provide any apparent reason to practice the presently claimed subject matter with a reasonable expectation of success. *See KSR v. Teleflex, Inc.,* No 04-1350 at 4, 14 (U.S. Apr. 30, 2007) ("A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art"). Mainly, Kelly fails to teach or suggest a composition in which formononetin represents at least about 90% of the isoflavone content, and further provides no apparent reason to alter any of its compositions to emphasize the presence of formononetin, especially for the treatment of ***post***-menopausal symptoms, as presently claimed.

For one, Examples 2 and 4 of Kelly, as relied upon by the Examiner, teach a ***composition*** that is structurally different from that of the instant claims (*i.e.,* about 95% daidzein in Kelly v. about 90% formononetin in the instant claims). Further, Example 4 of Kelly relates to a different ***use*** of that different composition. Mainly, Example 4 of Kelly relates to the use of soya hypocotyl powder in the treatment of ***menstruating***, or ***pre***-menopausal, women (*see* page 20, second to last paragraph of Kelly). In contrast, the instant claims relate to the treatment or reduction of menopausal symptoms in ***post***-menopausal woman, or women experiencing a different physiological state than the women of Example 4 in Kelly with an entirely different composition. As previously made of record, the intended therapeutic use of a novel compound or composition is highly relevant to patentability, and, therefore, must be considered in determining whether a person of ordinary skill in the art would have had any apparent reason to make the same with a reasonable expectation of success. *See Takeda Chemical Industries v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007). Here, the limited use of soy hypocotyl powder in ***pre***-menopausal women provides no apparent reason or reasonable expectation that an

entirely ***different composition***, in which formononetin represents at least about 90% of the isoflavone content, would have been considered useful in ***post-***menopausal women.

Further to these different uses, and with regard to any use, Kelly provides no apparent reason to alter any of its compositions in the manner of the instant claims, specifically to emphasize the presence of formononetin (*e.g.,* 90% or more of the isoflavone content is formononetin). In this regard, Applicant respectfully submits that the Examiner misreads the statement in Kelly that teaches the unimportance of whether the isoflavones are in their methylated or demethylated forms. In contrast to the Examiner's reading, Applicant believes that this statement leads away from a composition that is composed mainly of formononetin, or in the least provides no apparent reason that such a compound would have been considered useful in the treatment or reduction of menopausal symptoms in a post-menopausal woman. For instance, in teaching the ***unimportance*** of whether the isoflavones are present in the methylated or demethylated forms, a plain reading of Kelly suggests that there is simply no reason to alter the 95% daidzein (soy hypocotyl powder) composition of that reference in a manner that emphasizes formononetin, because no benefit would derive from such an "***unimportant***" alteration. Indeed, by further teaching that formononetin is the least oestrogenically active of all the isoflavones, and that demethylated daidzein has improved biological efficacy over formononetin, Kelly ***explicitly*** suggests that there would be no benefit to utilizing a composition of at least about 90% formononetin, as presently claimed. If anything, as previously made of record, Kelly relies mainly on genistein and daidzein, and teaches that it is prudent that these isoflavones be present in approximately equal proportions, explicitly leading persons skilled in the art down a different path (*e.g.,* towards a genistein-based composition), and implying that the presently claimed, formononetin-based compounds would have little, if any therapeutic biological activity. For these reasons, and contrary to the Examiner's assertion (*see* the Action, pages 7-8, carryover sentence), it is respectfully submitted that 90% daidzein does ***not*** suggest 90% formononetin, especially in view of Kelly as a whole. In this manner, Applicant submits that Kelly fails to provide any apparent reason to practice the subject matter of the instant claims with a reasonable expectation of success, and hence, fails to establish a *prima facie* case of obviousness over these claims.

Given the deficiencies in Kelly, which provide no apparent reason to use a composition of at least 90% formononetin (of the isoflavone content) in the treatment or reduction of menopausal symptoms in a post-menopausal woman, Applicant submits that the instant claims satisfy the requirements of non-obviousness over Kelly, and respectfully requests withdrawal of this rejection under 35 U.S.C. § 103(a).

Applicant believes that all of the claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/Mark E. Rogel/
Mark E. Rogel, J.D.
Registration No. 64,911

WTC/MER:rp

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

1536866_1.DOC